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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/748,389

12/29/2003

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21058/0206773-US0

8159

75172 7590 02/20/2008

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EXAMINER

WRIGHT, PATRICIA KATHRYN

ART UNIT

PAPER NUMBER

1797

MAIL DATE

DELIVERY MODE

02/20/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/748,389	Applicant(s) YAMAKAWA ET AL.	
	Examiner P. KATHRYN WRIGHT	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 January 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 8-22, 29-40, 55-64 is/are pending in the application.
- 4a) Of the above claim(s) 55, 58, 60, and 63 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,8-22,29-40,56,57,59,61,62 and 64 is/are rejected.
- 7) ☒ Claim(s) 57 and 62 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 December 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 30, 2008 has been entered.

Status of the Claims

2. This action is in response to papers filed January 30, 2008 in which claims 1 and 22 were amended, claims 3-7, 24-28 and 41-54 were canceled, and claims 55-64 were added. The amendments have been thoroughly reviewed and entered.

Applicant's arguments have been thoroughly reviewed but are deemed moot in view of the amendments, withdrawn rejections, and new grounds for rejection. New grounds for rejection, necessitated by the amendments, are discussed.

Election/Restrictions

3. Newly submitted claims 55, 58, 60 and 63 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the microfluidic device of group I, claims 1-50 contained three patentably distinct species. Species i is directed to field-force /gradient mechanism (corresponding to original claims 1-2, 8-3 and 29-40); species ii and iii are directed to molecular trapping mechanism (corresponding to original claims 3-7, 24-28, 41-48, and 49-50). New

claims 55, 58, 60, and 63 are directed at non-elected species ii and iii (i.e., essentially correspond to original claims 4-5). That is, claims 55, 58, 60 and 63 are directed to molecular trapping mechanisms. Applicant elected Group I, species i(a), see reply filed on August 15, 2007.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 55, 58, 60, and 63 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 1, 8-22, 29-40, 56-57, 59, 61-62 and 64 are under examination.

Drawings

4. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character “101” has been used to designate both the “sensor” and “porous membrane”, see paragraph [0026].

5. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

6. Claims 57 and 62 are objected to because of the following informalities: claims 57 and 62 contain a typographical error, "hallow" should be changed to --hollow--. Appropriate correction is required.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1, 8-9, 22, and 29-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 22 recites, *inter alia*, a porous membrane. Claims 8 and 29 recite the device further comprising a sensor. Claims 9 and 30 recite the porous membrane is the sensor. It is not clear how the "sensor" differs from the "porous membrane". Furthermore, the specification appears to refer to the porous member and sensor as the same element "porous membrane/ sensor 110", paragraphs [0023] and [0026]. The recitation of the same element under different names in different parts of the claim or the use of same term to refer to different elements is indefinite. The same term should be used for an element each and every time it is recited.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. Claims 1, 8-12, 15-22, 29-33, 36-40, 56, 59, 61 and 64 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent Pub. No. 2003/0136679 to Bohn et al., hereinafter "Bohn".

Regarding claims 1, 22, 29, 56, and 61 Bohn teaches a microfluidic device 20 comprising a source fluid flow channel 28 formed in lower substrate 24 and a target fluid flow channel 30 formed in the upper substrate 26. Note that the source fluid channel could be disposed in upper substrate and the target fluid could be disposed in the lower substrate and the device would function the same. The target fluid flow channel is in fluid communication with the source fluid flow channel at a cross-channel area. As shown in Fig. 1, the source fluid flow channel 28 crosses over the target fluid flow channel 30 in an "X fashion" at the cross-channel area (i.e., perpendicular, see paragraph [0039]; claim 21).

The Bohn device also includes a porous membrane 22 integral with the substrates 24, 26 (claim 18) and separating the source fluid flow channel from the target fluid flow channel in the cross-channel area and a field-force/gradient mechanism 50 proximate the porous membrane (see Figs. 1, 4-5c). The field- force/gradient mechanism generates an electric field to produce a fluid movement of a fluid from the source fluid flow channel to the target fluid flow channel via the porous membrane located in the cross-channel area, see paragraphs [0027], [0031]-[0033], [0060]-0064].

Regarding claims 8-9, and 29-30, as best understood, the porous membrane 22 exhibits sensing characteristics (sensor) causing a change in at least one of an optical and electrical characteristic in response to exposure to one or more particular solutes and/or analytes.

As to claims 10 and 31, Bohn teaches fluorescence spectroscopy and imaging (light source and detector) focused at the membrane 22 see paragraph [0060].

With respect to claims 11 and 32, Bohn also teaches the membrane 22 having a thickness 46 between 1 μm and 100 μm , within the claimed range of 0.01 and 50 micrometers (see paragraph [0026]).

Regarding claims 12 and 33 the porous membrane 22 of Bohn is capable of fractionating molecules based on size, molecular weight, charges, chemical affinity (see for example paragraphs [0060]-[0065]).

As to claims 14, 16 and 37, Bohn teaches the substrates 24, 26 made of silicon or polydimethyl siloxane (PDMS), see paragraphs [0025], [0039].

Regarding claims 19-20 and 39-40, please note that a recitation with respect to the manner in which a claimed apparatus is intended to be employed, (i.e., disposed or reused) fails to differentiate the claimed apparatus from a prior art apparatus if the prior art apparatus teaches all the structural limitations of the claim. *Ex parte Masham*, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987).

As to claim 59 note that Bohn teaches array of multiple paths formed from a plurality of source and target fluid channels (see Fig. 9b and paragraphs [0023] and [0058]).

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

13. Claims 13-14, and 34-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent Pub. No. 2003/0136679 to Bohn in view of US Patent No. 6,248,539 Ghardiri et al., hereinafter ("Ghardiri").

As discussed above, Bohn does teach the use of a nanoporous membrane 22, preferably made of polycarbonate. Bohn also teaches the membrane could be made of other material without departing the from the scope of the invention, see paragraph [0026].

Bohn does not specifically teach the membrane being made of single crystal or porous polysilicon membrane.

Ghardiri teaches a microfluidic device having a porous layer or membrane integrally formed on a single crystalline, or amorphous silicon substrate. The use of the porous silicon membrane makes possible the highly sensitive detection, identification

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and quantification of small analyte molecules at low concentrations (see col. 3, lines 59-63 and col. 5, lines 21+). Like the membrane used in the instant invention, the thickness of the Ghardiri membrane is between the range of 0.5 to 30 microns, see col. 3, lines 30+. The system of Ghardiri also includes a light source and CCD detector in communication with data collection equipment that collects data pertaining to changes in the optical characteristic of the porous membrane.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time of the claimed invention substituted the membrane of Bohn with the porous silicon membranes of Ghardiri, since Ghardiri teaches that the use of the porous silicon membranes makes possible highly sensitive detection, identification and quantification of small analyte molecules (see abstract).

14. Claims 57 and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bohn (US Patent Pub. No. 2003/0136679).

As discussed above, Bohn does teach the use of a nanoporous membrane 22 disposed between the upper and lower substrates 24, 26. Bohn does discuss the desirability of placing the nanoporous membrane between the upper and lower substrates without wrinkling or deforming the membrane and sufficiently holding the membrane in place for subsequent handling, but not so tightly as to permanently bond the membrane to the carrier (see paragraph [0042]).

Bohn do not teach the membrane being located in a hollow space formed by the first and second cavities or recessing in the upper and lower substrates. However, it would have been obvious to one ordinary skill in the art at the time of the claimed invention to form a first cavity and second cavity in the upper and lower substrate so

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that the membrane is located in a hollow space (recess) created by the first and second cavities in the upper and lower substrate, since the hollow cavities in the upper and lower substrates would help hold the nanoporous membrane in place for subsequent handling and prevent wrinkling or deforming the membrane.

Double Patenting

15. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

16. Claims 1, 8-22, 29-40, 56-57, 59, 61-62 and 64 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 7-11 and 23-24 and 30 of U.S. Patent No.6,606,543 to Yamakawa et al. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 7-11 and 23-24 and 30 of the US Patent no. 6,606,543 are directed to the same subject matter and fall entirely within the scope of claims 1, 8-22, 29-40, 56-57, 59, 61-62 and 64 of the instant application.

Both the present application and the US Patent no. 6,606,543 claim an apparatus comprising a substrate having defined therein, an upper microfluidic channel passing through the substrate along a first direction and a lower microfluidic channel passing through the substrate along a second direction. At least a portion of the lower microfluidic channel passes beneath a portion of the upper microfluidic channel to form a cross-channel area. Both require a porous membrane disposed between the upper and lower microfluidic channels proximate to the cross-channel area to form a semi-permeable barrier between the upper and lower microfluidic channels. Furthermore, both recite an apparatus further comprising a light source to direct a light toward the porous membrane and a detector to receive a portion of light reflected off of and/or emitted by the porous silicon membrane to detect the change in the optical characteristic of the porous membrane.

17. Claims 13-14 and 34-35 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 38-39 and 41 of copending Application No.10/856,372. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 38-39 and 41 of the copending Application No.10/856,372 are directed to the same subject matter and fall entirely within the scope of claims 13-14 and 34-35 of the instant application.

Both the present application and copending Application No.10/856,372 claim an apparatus comprising an upper substrate member having at least one upper microfluidic channel passing through the upper substrate member along a first direction and a lower substrate member having at least one lower microfluidic channel passing through the lower substrate member along a second direction. Both claim at least a portion of the

lower microfluidic channel passing beneath a portion of the upper microfluidic channel to form a cross-channel area. Both claim at least one porous membrane disposed and sandwiched between the upper and lower substrate members proximate to the cross-channel area to form a semi-permeable barrier between the upper and lower microfluidic channels. The at least one porous membrane is made of porous nanocrystalline silicon or porous polysilicon. Both the present application and copending Application No.10/856,372 claim a light source to direct light toward the porous membrane, and a detector to detect the change in the optical characteristic of the porous membrane.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

18. Applicant's arguments with respect to claims 1, 8-22, 29-40, 56-57, 59, 61-62 and 64 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

19. No claims are allowed.

20. The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure as general background information related to Applicant's field of endeavor.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to P. Kathryn Wright whose telephone number is 571-272-

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2374. The examiner can normally be reached on Monday thru Thursday, 9 AM to 6 PM, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

pkw

/Jill A. Warden/
Supervisory Patent Examiner, Art Unit 1797